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10/510,497	10/07/2004	Shunji Hayashi	Q84102	1554
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SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213			EXAMINER BADR, HAMID R	
			ART UNIT	PAPER NUMBER
			1781	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/510,497	Applicant(s) HAYASHI ET AL.	
	Examiner HAMID R. BADR	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6.9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6.9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/27/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed 10/8/2010 is acknowledged.

Rejection of claims 6, 9 and 10 under 35 U.S.C 112 first paragraph is withdrawn per applicants amendment.

Rejection of Claims 6, 9 and 10 under 35 U.S.C 112 second paragraph is withdrawn per applicants amendment.

New ground of rejection under 35 U.S.C. 112 second paragraph is set forth below necessitated by applicants' amendment in claim 6.

Two declarations by Mr. Matsuo dated 10/5/2010 have been considered. Examiner's comments are found under "Response to Arguments".

Claims 6 and 9-10 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 6 is indefinite for "wherein the additional yeast extract added is in an amount of 0.05 to 0.2% per liter of the raw milk". The concentration of yeast extract as recited is in error. The concentration is expected to be recited either in percentage e.g. 0.05-0.2% (w/w or w/v) or in unit weight per liter of raw milk e.g. 0.05 to 0.2 g per liter.

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According to Example 3, 20 g yeast extract is added to 20 kg of milk, therefore, the concentration should be 2 g per liter of the milk. Correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner et al. (1998, Development of a probiotic cheddar cheese containing human –derived *Lactobacillus paracasei* strains; hereinafter R1) in view of Anderson et al. (US 3,852, 158; hereinafter R2), Germond et al. (WO 0188150, hereinafter R3) and Kimura et al. (EP 1 112 692 A1, hereinafter R4).

3. R1 reports the results of a research on the preparation of cheddar cheese containing live cultures of probiotic *Lactobacilli*. R1 confirms that *L. paracasei* strains grew and sustained high viability in cheese during ripening. (Abstract).

4. R1 discloses the process of producing the cheese where an inoculum of starter cultures is added to the pasteurized milk. In addition to the starter culture, a probiotic culture such as *L. paracasei* is also added. Cheddar cheese is then produced according to the standard process known in the art. Preparation of the curd, cutting and cooking the curd are all standard processes as taught by R1. The curds are pressed and kept as pressed overnight. The cheese is then removed from mold, vacuum packed and

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ripened at 8C for approximately 8.5 months. (page 2193, Col. 1, Cheddar cheese manufacture).

5. Given that R1 teaches of the cheese being kept under press at ambient temperature (20-30C) overnight, it is clear that the bacteria, in the cheese, are exposed to temperatures and for the duration of time as presently claimed. Therefore keeping the pressed curd overnight, at ambient temperature (as disclosed by R1), is practically an incubation process which is carried out (per R1) before cooling the curd to 8C and keeping for approximately 8.5 months. It is clear that the incubation of the pressed curd at 20-35C for 16-26 hours before cooling the pressed curd, as presently claimed, is intrinsic in the process of R1.

6. R1 discloses that cheese made with *L. paracasei* contained high levels of these probiotic strains after 8 months of ripening with final counts of 10^7 - 10^8 CFU/g cheese. (page 2195, Col. 1, last two lines to Col. 2, first two lines). Given that R1 is concerned with the number of live bacteria after 8 months of cold storage, it is obvious that keeping cheese conditions to have high survival rates of the probiotic bacteria is motivated.

7. R1 concludes that the probiotic *L. paracasei* strains incorporated into cheddar cheese are found to grow and proliferate to high cell numbers in cheese over 8 months even when they are added at a relatively small inoculum. R1 further discloses that the results of the present study indicate that Cheddar cheese offers potential as an effective vehicle for delivery of these strains to the consumer. (page 2198, Col. 1, Conclusion)

8. While R1 discloses the viability of certain probiotics in cheese as a delivery matrix, R1 is silent regarding the addition of yeast extract to the starter culture prior to

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activation of the culture. R1 is also silent regarding the incorporation of *Lactobacillus gasseri* into the cheese.

9. R2 discloses adding yeast extract to the starter cultures normally used in the manufacture of cheese. (Col. 2, lines, 3-7, 17-18, 36-47). R2 discloses that the media for activation and growth of the cheese starters contain 0.1-.2% yeast extract (Examples). Therefore, step (1) in claim 6 was known in the art at the time the invention was made.

10. It is noted, in the presently claimed invention, that yeast extract is being added to the medium for activation and growth of the starter culture and *Lactobacillus gasseri* which will be eventually added to the cheese milk. It is also noted, in the presently claimed invention, that yeast extract is added to the cheese milk as well. However, since milk is very low in the concentration of amino acids, unsupplemented milk does not support the growth of *Lactobacillus gasseri*, therefore, the cheese milk itself should obviously be supplemented with yeast extract. Since R2 discloses the yeast extract concentration in the activation and growth medium at 0.1-0.2%, it would be obvious to add yeast extract to the milk at 0.1-0.2% as presently claimed.

11. Given that the utilization of yeast extract in cheese making is disclosed by R2, the addition of yeast extract to the starter culture medium or the milk (for cheese making) at any stage prior to the formation of curd would be obvious because the milk is still in a liquid state and mixing and uniform distribution of yeast extract in the milk will be assured. Therefore, adding yeast extract before curd formation, as presently claimed, would be obvious.

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12. R2 is silent regarding the incorporation of *Lactobacillus gasseri* in cheese.
13. R3 discloses the incorporation of *L. gasseri* in dairy products including cheese.
(page 3, lines 28-30; page 6, lines 2-4; claims 8-11)
14. R3 discloses the food compositions containing the probiotic organisms including *L. gasseri*. Therefore, employing cheese as a delivery vehicle for *L. gasseri* would have been obvious to an artisan.
15. R4 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori*, in foods [0001].
16. R4 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of 10°C and viable count of more than 10⁷ cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be intrinsically high. Consequently the limitation of claim 6 regarding the viable counts after a certain period of time at specific temperature will depend on how many viable bacteria are initially present. Adding yeast extract, as disclosed by R2, assures a high initial population in the cheese which will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.
17. R1 discloses the incorporation of probiotics in cheese where they can have a high rate of viability and recommends using cheese as a suitable vehicle to deliver such probiotics to consumers. R2 teaches of the addition of yeast extract or yeast

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autolysate for the activation and propagation of normal cheese starter cultures. The requirement, of *Lactobacillus gasseri*, for yeast extract regarding growth and proliferation was also known in the art at the time the invention was made. R3 teaches of using cheese as a delivery system for *L. gasseri*. R4 clearly discloses the anti *Helicobacter pylori* properties of *Lactobacillus gasseri* strain OLL 2716 and how dairy foods may be used containing this probiotic. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to follow the teachings of R1 to make a cheese containing a probiotic and add yeast extract to the starter culture and the raw milk as taught by R2 and choose cheese as a delivery system for *L. gasseri* as taught by R3. The *L. gasseri* strain (OLL 2716) which has anti *H. pylori* properties would have been selected logically for that benefit, as taught by R4. One would do so to produce a cheese which can contain a high number of a probiotic organisms such as *Lactobacillus gasseri* and use it as an efficient matrix for delivery of probiotics to the consumers. Absent any evidence to the contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success to incorporate a probiotic organism such as *Lactobacillus gasseri* in cheese as presently claimed.

Response to Arguments

Applicants' arguments have been reviewed. These arguments are not persuasive for the following reasons.

1. Mr. Matsuo states that a constant high bacterial count of lactic acid bacteria, after 6 month of storage, is an unexpected and unpredicted result.

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a. The concept of sustaining high probiotic counts is motivated by R1. Please see the disclosure by R1. Secondly, to have high counts of the target organisms, the initial population should be set high which is a known fact in the art. The *L. gasseri* requires yeast extract for growth, therefore to grant the high initial population, yeast extract is obviously needed for growth and maintenance. In light of the teachings of the cited references, results are neither unexpected nor unpredicted.

2. Mr. Matsuo states that after calculations, the amount of added yeast extract, as disclosed by R2, is 0.000825-0.01165%. He further adds that the amount of R2 is far less than 0.05 % which is the lower limit of the amount of yeast extract recited in claim 6 of the instant application.

a. As explained above. The growth media needs 0.1-0.2% yeast extract in light of the teachings of R2. It was also known in the art that *L. gasseri* requires yeast extract for growth. Therefore, the cheese milk, being also considered as growth medium, requires supplementation with yeast extract at 0.1-0.2% as presently claimed. Furthermore, R2 is being cited in an obviousness type rejection. Any information express or implicit, provided by the reference will make the instant case obvious.

3. Applicants argue that when cheese containing lactic acid bacteria is produced according to conventional method, bacterial count in cheese is decreased during preservation.

a. Depending on the species of lactic acid bacteria, the above statement may be true. However, for species such as *L. gasseri*, which definitely need yeast extract for growth, the presence of yeast extract at predetermined concentrations would assure

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growth and maintenance during the storage time so that the resulting ripened cheese will still have live counts.

4. Applicants argue that high survival rates would be only assured if yeast extract is added to the milk and the pressed cured is incubated at specific conditions.

a. In light of the teachings of the references and the information available to the artisan addition of yeast extract to milk is obvious. R1 also teaches of keeping the pressed cheese at ambient temperature for durations similar to the presently claimed conditions. Therefore, one would expect to get enough number of organisms after 6 months of storage at the claimed temperature of storage.

5. Applicants argue that if survival rate of lactic acid bacteria in cheese is not necessary, yeast extract is not added.

a. As stated in the rejections above, *L. gasseri* needs yeast extract for growth to being with. Therefore, maintenance and survival of this organism in cheese will depend on the addition of yeast extract.

6. Applicants argue that references do not disclose addition of 0.05 to 0.2% yeast extract.

a. R2 clearly discloses adding 0.1-0.2% yeast extract into the medium. Since the cheese milk is also considered a growth medium and noting that *L. gasseri* does not grow without supplementing milk with yeast extract, adding 0.1-0.2% yeast extract to the cheese milk would have been obvious.

7. Applicants argue that Anderson (R2) does not disclose or teach the instantly claimed amount of yeast extract.

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a. Anderson teaches of adding between 0.1-0.2% yeast extract to the growth medium. Cheese milk is logically considered a growth medium. Therefore, to assure proper growth of *L. gasseri* in milk, it needs to be supplemented with yeast extract at levels disclosed by Anderson.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,578,988 to Hori et al. This reference discloses the addition of starter culture to raw milk (Example 2).

JP 2001-000143-A: Incorporation of *L. gasseri* OLL 2716 into food products for anti *H. pylori* effect.

JP H08-116872-A: Promoting the proliferation of *Lactobacilli*.

JP H07-236484-A : Incorporating *L. gasseri* into cheese.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781